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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,554	03/03/2000	Jacob Vroman	AIMPORT.011A	7420

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,554	VROMAN, JACOB	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,27-32 and 36-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,27-32 and 36-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment and Applicant's Arguments/Remarks, both filed 04/28/05 is acknowledged.

Claims 23, 24, 27-32 and 36-45 are pending. Claims 23, 27, 28 and 42 have been amended. Claims 25 and 26 have been cancelled. Claims 23, 24, 27-32 and 36-45 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23, 24, 27-32 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siddiqui (US Pat. No. 6,146,664).

Siddiqui teaches an ascorbic acid – (Vitamin C) composition in a non-aqueous or substantially anhydrous silicone vehicle having superior stability, a high degree of bioavailability and effectiveness, for use in topical applications to reduce wrinkles, increase collagen growth and elasticity and for treating UV exposure, whereby the ascorbic acid is contained in an amount of 0.1% to 40% by weight. The composition also comprises exfoliants, such as Vitamin A in the form of retinol or its esters or acids, for example retinyl palmitate or retinoic acid (see Abstract); (column 2, line 45 – col. 4, line 25); Tables and Examples. A method of improving skin appearance using the ascorbic acid (Vitamin C) composition is also taught.

According to Siddiqui, the solid ascorbic acid is substantially completely insoluble in the silicone-based vehicle, and the vehicle provides an ideal reservoir for delivering the ascorbic acid into the skin where it is soluble in the moisture-laden levels of the skin. It has been unexpectedly found that the combination of the solid ascorbic acid dispersed in the silicone-based vehicle delivers the intended effect on the skin while simultaneously being safe and effective (col. 2, lines 48-60).

Siddiqui teaches that the particulate ascorbic acid consists essentially of solid ascorbic acid particles having a particle size of less than about 20 microns (μm), for example less than about 12 (μm) (instant claims require no greater than ~5(μm)) (col. 3, lines 52-54). The preparation also contains materials, such as other vitamins, cosmetic and herbal ingredients and/or medicaments as desired (col. 2, lines 64-67).

The examples demonstrate various preparations comprising ascorbic acid. For instance, Table 2 exemplifies a method of making the ascorbic acid preparation by combining Polysilicone 11, dimethicone, cyclomethicone, tocopheryl acetate and retinyl palmitate whereby solids of ascorbic acid are dispersed into this mixture with appropriate agitation. The ascorbic acid is ground into the mixture using a three-roll mill to obtain a solids ascorbic acid particle size of less than 12.5 microns. Example 6 at columns bridging 6-7 demonstrate the testing of a product for antioxidant activity using ultraviolet light. Siddiqui teaches at col. 7, lines 6-8, that the exposure of the skin to ultraviolet (UV) light is known to generate free radicals in skin cells. Various endpoints were used to measure the antioxidant activity. The data from these endpoints were compared to a negative control (cell cultures exposed to UV light without presence of antioxidants) and a positive control (cell cultures not exposed to UV light). The results clearly indicated that the ascorbic acid formulation exhibits antioxidant activity. Alternative procedures are also disclosed.

The similarities to the process of making the prior art's composition and the claimed invention is noted in that the instant application teaches that the L-ascorbic acid powder is particulate and can be prepared by grinding, etc., in the absence of any teachings for positive steps to alter the pH of the solid ascorbic acid (see pg. 4, lines 6+ of the instant application). Note that Siddiqui uses ascorbic acid as Vitamin C (Abstract and column 1, lines 6 and 13). As such, the ascorbic acid taught by Siddiqui is L-ascorbic acid.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide UV protection or treat wrinkles or to stimulate collagen production in a mammal by topically applying a Vitamin C composition of Siddiqui having at

least 30% L-ascorbic acid, by weight, and a non-aqueous carrier, since Siddiqui discloses that his formulation that contains 0.1% to 40% or higher has been found to have a high degree of bioavailability and effectiveness as a topical application with the expectation of successful treatment or therapy, as similarly desired by the applicants. Furthermore, the reference appears to teach that these benefits and effective concentrations for topical applications are well known for Vitamin C formulations (see cols. 1 & 2). The reference discloses that challenges have been how to formulate stable topical formulations of Vitamin C, particularly at the higher concentrations needed for maximum activity (col. 2, lines 15-20). Hence, the instant invention is rendered obvious and unpatentable over the teachings of Siddiqui.

Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siddiqui (US Pat. No. 6,146,664) in view of Ozlen (US Pat. No. 5,441,740).

The teachings of Siddiqui ('664) are delineated above. Siddiqui teaches exfoliants such as Vitamin A in the form of retinol or its esters or acids, for example retinyl palmitate or retinoic acid (see col. 4, lines 3-7). Siddiqui do not teach an enzymatic exfoliant, such as papain.

Ozlen ('740) teaches topical cosmetic compositions and methods of treating and alleviating skin conditions, such as skin slackness, wrinkles and dry skin comprising hydroxy acids, salicylic acid and digestive enzymes comprising a mixture of bromelain and *papain* derived from fruit extracts. The papain and bromelain digestive enzymes work synergistically to gently lift and remove older, upper layers of skin, revealing the fresher, younger skin cells beneath. The bromelain and papain digest the proteins in skin cells refining coarse, thickened

skin for a smoother textured appearance. According to Ozlen, this dual action approach gives more *effective exfoliating results* while maintaining the mildness of the alpha hydroxy acid/salicylic acid combination. Cosmetic benefits are improved skin tone, softer, smoother skin, fading of age spots, diminished fine lines and wrinkles and a finer, improved texture and appearance attributed to the exposure of the underlying layers of the skin. In addition to the exfoliating benefits of the composition, other advantages of the product are that it does not increase sensitivity to the sun, help's increase skin elasticity and moisture retention and may help increase skin's production of natural humectant, and is suitable for all skin types (see reference col. 2, line 7 – col. 4, line 53).

Example 1 on columns 3-4 demonstrates a cosmetic formulation comprising various ingredients that include papain, hydroxy acids, retinyl palmitate (Vitamin A), antioxidants, minerals and the like.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include enzymatic exfoliants, such as the papain of Ozlen within the cosmetic formulation of Siddiqui because Ozlen teaches topically applied cosmetic compositions of hydroxy acids, enzymes (*i.e.,* papain), vitamins (*i.e.,* Vitamin A-retinyl palmitate) and antioxidants for treating various skin conditions (*i.e.*, skin firmness, wrinkles, dry skin) whereby the enzymatic exfoliant, papain offers effective exfoliating results by lifting and removing upper layers of skin for a smoother textured appearance with no increase in sensitivity to the sun and similarly, Siddiqui teaches a cosmetic composition comprising exfoliants, such as Vitamin A (*i.e.*, retinyl palmitate), antioxidants and the like for use in topical applications to treat skin conditions, such as reducing wrinkles, increasing collagen growth and elasticity and treating UV exposure. The expected

result would be an enhanced cosmetic formulation that provides greater exfoliating benefits for better skin conditions.

Claims 23, 24, 27-32 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hernandez *et al.* (US Pat. No. 5,843,411).

Hernandez *et al.* teach a stable composition and method of treating and/or preventing photo-aged skin, sunburn, wrinkles and related skin disorders by topically applying to affected areas of the skin, the treatment composition containing an effective amount of a compound such as ascorbic acid, derivatives of ascorbic acid and/or extracts containing ascorbic acid, in a pharmaceutically acceptable vehicle containing a substantially anhydrous base having no water added, wherein the ascorbic acid is contained in a concentration of 0.1% by weight to 95% by weight (see Abstract, column 2, lines 63-65); (col. 3, line 20 – col. 5, line 34).

According to Hernandez, the substantially anhydrous base protects the ascorbic acid, or its derivatives and/or extracts containing ascorbic acid, from degradation, instability, loss of potency and loss of color. The composition may also contain preservatives, humectants, pH buffers and carrier solvents. Certain pH buffers, such as alkaline sodium citrate and magnesium citrate and solvents may also function as a substantially anhydrous base. The resultant mixture is a smooth feeling delivery vehicle, which delivers the ascorbic acid (or its derivatives) to the skin in an effective and stable manner (col. 3, line 55 – col. 4, line 17).

Other substantially anhydrous compositions, with no water added, may be substituted for the silicones, such as other emollients, including esters, amides, ethoxylated fats, mineral oil,

petrolatum, vegetable and animal fats. Substantially anhydrous synthetic waxes, such as triglycerides and tribehin may be utilized (col. 5, lines 4-12).

Hernandez states that ascorbic acid, or its derivatives, esters of ascorbic acid, amides of ascorbic acid, L-ascorbic acid, known as Vitamin C, or other derivatives or related compounds which may supply L-ascorbic acid or its derivatives, is applied in a pharmaceutically acceptable vehicle, in a concentration of from 0.1% to 95% by weight, preferably 10-15% by weight, generally by frequent periodic application, such as by a once or twice daily application (col. 4, lines 33-47).

The examples at columns 5 & 6 demonstrate topically applied skin care products comprising ascorbic acid. Moreover, Table I shows the stability of examples of the composition, using ascorbic acid, specifically L-ascorbic acid at 10%.

The reference teaches that the ascorbic acid formulation is in a non-aqueous base or substantially anhydrous composition (col. 3, lines 60-67) containing silicones and derivatives of silicone chemistry (col. 4, lines 60 – col. 5, line 65).

Regarding the instantly claimed particle sizes, it is deemed obvious to one of ordinary skill that suitable ranges could be determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Furthermore, the prior art teaches and recognizes that L-ascorbic acid and Vitamin C are known to be effective for prevention of UV damage to the skin and act as an anti-oxidant to counteract the skin damage ranging from transitory sunburn to permanent wrinkles from photo-aged skin (col. 1, lines 24-30), wherein Hernandez *et al.* invented a way to stabilize ascorbic acid and the

derivatives having similar utilities. Hence, the instant invention is rendered obvious and unpatentable over the teachings of Hernandez *et al.*

Prior Art made of record and deemed relevant by Examiner:

Gardner US Pat. No. 5,516,517 (05/1996):

Gardner teaches a skin treatment process designed to reduce the aging process of skin comprising digestive enzymatic exfoliants of papain and vitamins, such as Vitamin A, E.

Response to Arguments

Applicant's arguments filed 04/28/05 have been fully considered.

Applicant's arguments are comprised of the following:

- Rejection of claims 23-32 and 36-45 under 35 U.S.C. §112, first paragraph: Claim 23 has been amended to recite 'decrease or alleviate'. The terms 'removal and prevention' have been deleted.

>>The 35 U.S.C. §112, first paragraph rejection over claims 23-32 and 36-45 has been *withdrawn* by virtue of the amendment.

- Rejection of Claims 23-45 under 35 U.S.C. §103(a) over Siddiqui (US '664): Applicant argues, "Siddiqui fails to teach or suggest an ascorbic acid composition of the instantly claimed particle size (no greater than approximately 5 μm) and the addition of an exfoliant to the described ascorbic acid composition."

>>Applicant's arguments have been fully considered, but were not persuasive. Siddiqui teaches an ascorbic acid – (Vitamin C) composition, wherein the ascorbic acid is contained in an amount of 0.1% to 40% by weight, which meets the instant concentration requirements (instant claim 23 recites 30% L-ascorbic acid) (see col. 3, lines 26-31). Siddiqui further teaches that the formulation comprises ascorbic acid particles having a particle size of less than about 20 microns (μm), for example less than about 12 (μm), which meets the instant particle size requirements of 'no greater than approximately 5μm'; (see col. 3, lines 52-54). It is pointed out that the 'less than about 12 (μm)' taught by Siddiqui would include particle sizes having approximately 5μm (or less) as desired by Applicant. Moreover, Applicant's have not demonstrated any unusual or surprising results of effects attributable to the claimed particle size of 'no greater than approximately 5μm'. The prior art clearly recognizes and teaches suitable particle sizes of ascorbic acid and further teaches that their formulations provide for superior stability, a high degree of bioavailability and effectiveness. The prior art recognizes how to formulate stable topical formulations of Vitamin C, particularly at the higher concentrations needed for maximum activity (col. 2, lines 15-20). Hence, given the teachings of Siddiqui, who teaches stable, bioavailable ascorbic acid compositions, the instant invention is rendered *prima facie* obvious to one of ordinary skill in the art.

- Rejection of Claims 36 and 37 under 35 U.S.C. §103(a) over Siddiqui (US '664) in view of Ozlen (US '740):

Applicant argues, "an ascorbic acid composition of a mean particle size of no greater than approximately 5 μm provides beneficial properties to the composition, that are neither taught nor suggested by Siddiqui or Ozlen".

>> Applicant's arguments have been fully considered, but were not persuasive. The beneficial properties (*i.e.*, greater solubility, absorption), which Applicant states are due to the small particle size and thus, greater surface area, are also obtained using the formulations of the prior art. As delineated above, Siddiqui's ascorbic acid formulation provides for particle sizes of less than about 20 microns (μm), for example less than about 12 (μm), and thus beneficial properties and effects would be obtained. Siddiqui also teaches that superior stability, a high degree of bioavailability and effectiveness is obtained using their formulation. Burden is shifted to Applicant to establish that the ascorbic acid particle sizes taught by Siddiqui would not in fact, provide for beneficial properties or results.

- Rejection of Claims 23-45 under 35 U.S.C. §103(a) over Hernandez *et al.* (US '411:

Applicant argues, "An ascorbic acid composition of a mean particle size of no greater than approximately 5 μm and the addition of an exfoliant provide beneficial properties to the composition, that are neither taught nor suggested by Hernandez. The Office Action provides no support for the proposition that 'it is deemed obvious to one of ordinary skill, to determine suitable particles sizes through routine or manipulative experimentation' and provides no support for beneficial properties of the claimed particle sizes, and thus one

skilled in the art would not have been motivated to obtain particle sizes in Applicants size range."

>> Applicant's arguments have been fully considered, but were not persuasive. Admittedly, while the exact particle sizes are not explicitly taught by Hernandez, it is noted that Hernandez does teach similar compositions comprising similar components as claimed, such as ascorbic acid and L-ascorbic acid (Vitamin C) for use in the same field of endeavor as Applicant. Hernandez also teach ascorbic acid in a concentration of from 0.1% to 95% by weight (col. 4, lines 33-47). Since the prior art teaches the use of the same components in similar amounts, formulated in essentially the same manner, it is expected that beneficial results would also be obtained. Moreover, with regards to concentrations and/or particle sizes, it is pointed out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (*i.e.*, enhanced degree of solubility) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Given the teachings of the prior art, which teaches effective vitamin C formulations and methods for treating skin conditions, as those claimed, it is the position of the Examiner that the

instant invention would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh

Patent Examiner

Art Unit 1615

June 27, 2005

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